

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(Southern Division)**

EXEGI PHARMA, LLC
90 Church Street
Rockville, Maryland 20850

Plaintiff,

v.

VSL PHARMACEUTICALS, INC.
13800 Coppermine Road
Herndon, Virginia 20171

Serve on: Douglas M. Nabhan
200 South 10th St. Ste 1600
Richmond, VA 23219

Defendant.

Case No.

COMPLAINT

Plaintiff ExeGi Pharma, LLC (“ExeGi”), by and through its undersigned counsel, as and for its Complaint against Defendant VSL Pharmaceuticals, Inc. (“VSL Inc.”), alleges as follows:

NATURE OF THE ACTION

1. This case is about just how far a massive pharmaceutical conglomerate will go to destroy an individual whose only mistake was trusting the company with his invention in the first place. Claudio De Simone (“Prof. De Simone”) created a unique eight-strain, high-potency probiotic formulation capable of managing and alleviating numerous health conditions (the “De Simone Formulation”). To ensure that the De Simone Formulation reached consumers, he licensed the distribution rights for the De Simone Formulation to VSL Inc. When Prof. De Simone’s product proved commercially successful, VSL Inc. reaped substantial dividends. Yet, for VSL Inc.,

that was not enough. To increase its bottom line, VSL Inc. pressured Prof. De Simone to manufacture a cheaper, inferior product. Prof. De Simone, recognizing the potential harm to the public, refused—and, eventually, took his “Know-How” (which was necessary to manufacture the De Simone Formulation) with him.

2. In the years to come, VSL Inc. would make him pay for it. VSL Inc. insisted that Prof. De Simone’s Know-How belonged to VSL Inc. alone. VSL Inc. claimed that Prof. De Simone had breached his fiduciary duty by “taking” his Know-How and by interfering with VSL Inc.’s ability to procure the De Simone Formulation from the manufacturer. For four years, VSL Inc. attacked Prof. De Simone and ExeGi Pharma, LLC (“ExeGi”), the start-up to whom he had subsequently licensed the De Simone Formulation, through litigation on these, and other equally baseless, allegations, until a federal judge and a unanimous jury rejected VSL Inc.’s claims in their entirety. Now, VSL Inc. has once again put its army of attorneys to the task of attacking Prof. De Simone and destroying ExeGi’s business by intentionally and wrongfully interfering with its business relationships.

3. The relationship between VSL Inc. and Prof. De Simone certainly did not begin this way. Prof. De Simone, a world-renowned scientist, inventor, and physician, is the inventor of the De Simone Formulation. The De Simone Formulation is a high-potency probiotic blend that consists of a unique, proprietary combination of eight strains of bacteria, manufactured pursuant to a specific, secret process. Prof. De Simone established VSL Inc. with two brothers, Claudio and Paolo Cavazza, nearly twenty years ago. Prof. De Simone licensed the rights to the De Simone Formulation (including both the rights to use the information in the related patent and the rights to use the accompanying Know-How required to actually manufacture the De Simone Formulation) to the new company. In 2002, the De Simone Formulation became available commercially, via

VSL Inc., under the trademark “VSL#3.” For portions of time between 2002 and 2014, Prof. De Simone served as VSL Inc.’s CEO and a member of its board of directors.

4. Despite this success (or, more likely, because of it), the business relationship between Prof. De Simone and the Cavazzas began to fracture. The Cavazza brothers and their heirs were intent on further increasing their profits, even if it came at the public’s expense. To that end, they tried to force Prof. De Simone to make a “fake” version of VSL#3 with cheaper ingredients at a new, Cavazza-owned manufacturer. However, Prof. De Simone knew that a new, fake product would pose a significant health risk to the many consumers who relied on VSL#3 to manage serious medical conditions such as pouchitis, ulcerative colitis, and irritable bowel syndrome, as the fake version would not have the proven safety and efficacy of the De Simone Formulation, which has been the subject of more than 60 published clinical studies and has a lengthy clinical history of success. Therefore, Prof. De Simone refused to assist the Cavazzas’ efforts; when he did, Paulo Cavazza threatened to “end his bloodline” and began to wage war against him in court in an effort to obtain access to the secret formula that comprised the De Simone Formulation. When that failed, the Cavazzas also attempted to surreptitiously access the secret formula. After all of this, Prof. De Simone was left with no choice; he resigned as CEO of VSL Inc.

5. While Prof. De Simone was under pressure from the Cavazzas and their managers to make a cheaper, untested product, the Cavazzas had secretly entered into an agreement with Alfa Wassermann. Per that agreement, the Cavazzas would merge their own company, Sigma Tau, with Alfa Wassermann to create a new company (which was to become “Alfasigma”) and that new company would receive the license to VSL#3. However, the terms of that deal—in particular, the earnings margin for VSL#3 that the Cavazzas promised—were such that it would not be possible to make a VSL#3 product according to the quality required by Prof. De Simone to make the De

Simone Formulation. This covert promise by the Cavazzas, and the further riches they expected from the Alfa Wassermann deal, was the real reason they exerted so much pressure on Prof. De Simone to change his successful product, despite the enormous risk to public health.

6. For a time after his departure, Prof. De Simone sought to continue selling the De Simone Formulation through VSL Inc. and Leadiant Biosciences, Inc. (“Leadiant”), but this time from outside the company and with greater assurances of the safety of his secret formula. However, VSL Inc. and Leadiant declined to cooperate. Prof. De Simone, therefore, decided to license the right to market and distribute the De Simone Formulation to a new company, ExeGi. VSL Inc. refused to accept this new reality and took the shocking position that it had owned the De Simone Formulation all along, a position that was belied by numerous agreements between the parties and a long course of dealing with one another. Again left with little other choice, Prof. De Simone was forced to protect his proprietary rights. In 2015, Prof. De Simone commenced suit against VSL Inc. in the United States District Court for the District of Maryland (the “District Court Action”)¹ before The Honorable Theodore D. Chuang. Prof. De Simone requested, among other things, a judicial declaration that he owned the Know-How. VSL Inc. and Leadiant responded by filing an extensive set of counter-claims.

7. In 2016, ExeGi, with its exclusive license to market and sell the De Simone Formulation in the United States, began to sell the De Simone Formulation under the brand name “Visbiome.” Danisco continued to manufacture Visbiome (just as it has manufactured the De Simone Formulation when it was sold as “VSL#3”) pursuant to a contract between ExeGi, Prof. De Simone, and Danisco.

¹ See *De Simone, et al. v. VSL Inc., et al.*, Case No. 8:15-cv-01356 (TDC).

8. ExeGi accurately advertised Visbiome as containing the eight strains comprising the De Simone Formulation. Prof. De Simone had previously (in 2011) authorized and instructed the deposit of ampoules containing physical isolates of these strains from Danisco in a “strain bank” in Germany (the “Deposited Isolates”). The isolates of each strain were deposited into a separate account and assigned a code by the strain bank (collectively, the “DSM Codes”). The DSM Codes were then, and always have been since, public information. Scientists frequently used the DSM Codes to describe the De Simone Formulation in their publications.² Accordingly, to accurately represent the contents of Visbiome to the public, ExeGi referenced the strains by their DSM Codes (which are public information) as well.

9. While ExeGi advertised its product truthfully, VSL Inc. attempted to reverse engineer the De Simone Formulation. When those efforts proved fruitless, VSL Inc., together with its licensees, Leadiant and Alfasigma USA, Inc. (“Alfasigma”), created a new product (the “Fake Formula”), which was a poor imitation of the De Simone Formulation, and simply began selling that product under the trademark “VSL#3” without telling the public that the formula had changed. In short, VSL Inc. had brought its plan to market and sell a “fake” formula to fruition. VSL Inc.’s licensees intentionally passed off the Fake Formula to consumers as equivalent to (and equally efficacious as) the De Simone Formulation, despite the fact that they had conducted no testing whatsoever to establish as much. Indeed, those claims were demonstrably false.

10. When Prof. De Simone and ExeGi became aware of this false advertising and the respective roles of Leadiant and Alfasigma, they added additional claims to the District Court Action, including claims against both Alfasigma and Leadiant for false advertising under the Lanham Act. VSL Inc., Alfasigma, and Leadiant (collectively, the “District Court Defendants”)

² A compilation of some such articles is appended as Exhibit A hereto.

brought a total of 52 counterclaims against Prof. De Simone and ExeGi. Among them was a claim against Prof. De Simone and ExeGi for false advertising and unfair competition under the Lanham Act and a claim against Prof. De Simone for breach of fiduciary duty. Although the District Court Defendants challenged various statements on ExeGi's packaging and packaging inserts as violating the Lanham Act, they never once contested ExeGi's references to the DSM Codes, which had appeared on ExeGi's packaging since 2016.

11. Separately, VSL Inc. claimed that Prof. De Simone had breached his fiduciary duty to VSL Inc. by, *inter alia*, "taking" the Know-How, which VSL Inc. insisted was its property. As VSL Inc. defined it, the Know-How was a "trade secret," and it included, among other things, the "biological materials" necessary to make the De Simone Formulation. Having already put the issue of the ownership of the Know-How (and the biological materials) before Judge Chuang, VSL Inc., through its parent company, Actial Farmaceutica S.r.l. ("Actial") and other related companies, filed numerous litigations throughout the world to (1) harass Prof. De Simone and exhaust his resources; and (2) play games to see if it could get some court, somewhere, to make a ruling in its favor. To that end, Actial sued Prof. De Simone in Italy (amongst other places), where Actial asked the Court of Rome to determine that it "owned" the Deposited Isolates, the ampoules containing the physical isolates of the bacterial strains used in the De Simone Formulation that Prof. De Simone had deposited in the strain bank in 2011.

12. After realizing that it was likely to lose the issue of who owned the Know-How, VSL Inc., after maintaining for years that the Know-How was its own "trade secret," pivoted in its summary judgment briefing before Judge Chuang and argued instead that the Know-How was not deserving of proprietary protection at all. On October 9, 2018, Judge Chuang issued a Memorandum Opinion rejecting VSL Inc.'s eleventh-hour argument and finding that Prof. De

Simone owned the Know-How. Judge Chuang also dismissed VSL Inc.'s claim for breach of fiduciary duty, to the extent it had been based on Prof. De Simone's misappropriation of the Know-How. Accordingly, VSL Inc.'s claim for breach of fiduciary duty was reduced to its claim about Prof. De Simone's actions in the few years prior to leaving the company in 2014, including that he had "secretly" taken control of the Deposited Isolates and inserted a provision into the supply contract between Danisco and VSL (the "2014 Danisco Supply Agreement") to wrongfully interfere with VSL Inc.'s ability to procure VSL#3 from Danisco. That claim went to trial, where it was also rejected; this time, by a unanimous jury.

13. On November 20, 2018, the jury unanimously determined that Prof. De Simone had not breached his fiduciary duty to VSL Inc. The jury also returned a verdict in favor of Prof. De Simone and ExeGi and against the District Court Defendants on the remaining counts. For Prof. De Simone's claims of breach of contract and unjust enrichment, and for ExeGi's claims of false advertising, the jury awarded them a combined \$18,014,041.00 in damages. The jury did not even get a chance to consider the District Court Defendants' false advertising and unfair competition claims against Prof. De Simone and ExeGi, because the District Court Defendants voluntarily dismissed those claims themselves, with prejudice, shortly before the conclusion of the trial. Judge Chuang entered the verdict the next day.

14. Despite this verdict, VSL Inc. and Alfasigma chose not to remove or revise VSL#3's false advertising and continued trying to sell VSL#3 with the same materially false claims that served as the basis for the jury's decision. However, their distributors, wholesalers, and even their e-commerce solution platform were not willing to go along for the ride; most of them stopped participating in the sale of VSL#3 as long as VSL Inc. and Alfasigma continued its false advertising. Sales of VSL#3 cratered.

15. In the meantime, Actial had continued advocating for its “ownership” of the Deposited Isolates before the Court of Rome—even though that claim was already conclusively rejected by the District Court in Maryland. On July 26, 2019, nine months after Judge Chuang had already awarded Prof. De Simone the Know-How in his Opinion resolving the parties’ motions for summary judgment, the Court of Rome published a declarative decision that Actial owned the Deposited Isolates. However, declarative decisions in Italy are merely preliminary rulings; they are not final and cannot be enforced. Declarative decisions do not even contain an order of any kind; indeed, there is no order that requires Prof. De Simone to “return” the Deposited Isolates to Actial. The Court of Rome’s “decision” would only become an order, and therefore become executable when, and if, it was confirmed by the Court of Appeals and the Supreme Court of Italy.

16. However, VSL Inc., desperate to stop the flood of customers who had abandoned VSL#3 in favor of Visbiome after the jury’s false advertising verdict, immediately tried to use this new inoperative decision to harm ExeGi’s business and help its own. First, counsel for VSL Inc. worked to disrupt ExeGi’s supply contract with Danisco. By letter, VSL Inc. purportedly advised Danisco of the Court of Rome’s decision, but grossly misrepresented the Court of Rome’s finding and failed to note that it was merely preliminary and hence not enforceable. VSL Inc. then demanded that, based on this erroneous explanation of the Court of Rome’s decision, Danisco must “immediately cease any further production or delivery of the Visbiome product to ExeGi” unless and until VSL Inc. received “confirmation” that Visbiome would not be “marketed, distributed or sold with any reference to the DSM codes.” Although VSL Inc. had never before contested ExeGi’s right to reference the DSM Codes, VSL Inc. suddenly made the ridiculous, specious claim that any use of (or reference to) the DSM Codes would constitute a “misappropriation of property rights” and amount to “false advertising.” VSL Inc. acknowledged

that Danisco manufactured Visbiome pursuant to a contract with ExeGi and Prof. De Simone. In short, VSL Inc. intentionally and wrongfully interfered with ExeGi's contractual and business relationship with Danisco.

17. Next, VSL Inc. sent similar letters to ExeGi, as well as to many of ExeGi's wholesalers and distributors. As with the letter to Danisco, VSL Inc. once again made the ridiculous claim that use of the DSM Codes violated VSL Inc.'s rights and that these entities too must cease selling Visbiome under threat of legal action by VSL Inc.

18. ExeGi now brings this action for a declaratory judgment declaring that ExeGi has the right to use and reference the DSM Codes in marketing, distributing, and selling Visbiome, and further declaring that ExeGi's references to the DSM Codes do not constitute false advertising or unfair competition under the Lanham Act. ExeGi also brings a claim against VSL Inc. for tortiously interfering with its business relationships and for unfair competition based on VSL Inc.'s efforts to jeopardize and to damage ExeGi's business through fraud, deceit, trickery, and other unfair methods. ExeGi seeks a permanent injunction barring VSL Inc.'s continuing interference.

THE PARTIES

19. Plaintiff ExeGi Pharma, LLC ("ExeGi") is a limited liability company organized under the laws of New York with its principal place of business at 90 Church Street, Rockville, Maryland 20850. The Members of ExeGi are citizens of Maryland and Switzerland.

20. Defendant VSL Pharmaceuticals, Inc. ("VSL Inc.") is a corporation organized and incorporated under the laws of Delaware with its principal place of business in Herndon, Virginia.

JURISDICTION AND VENUE

21. The sole Plaintiff in this action is a citizen of Maryland and Switzerland, and the sole Defendant is a citizen of Delaware and Virginia. Accordingly, there is complete diversity between the parties.

22. As the amount in controversy exceeds \$75,000.00, exclusive of interest and costs, this Court has jurisdiction under 28 U.S.C. § 1332(a)(1).

23. In addition, because this dispute concerns a federal question under Section 43(a) of the Lanham Act, this Court has jurisdiction under 28 U.S.C. § 1331.

24. This Court has personal jurisdiction over VSL Inc. because ExeGi's claims arise, in part, from VSL Inc.'s conduct in this judicial district.

25. Venue is properly laid in this judicial district under 28 U.S.C. § 1391(b)(1) because this Court has personal jurisdiction over VSL Inc., and VSL Inc.'s improper conduct, as alleged herein, occurred in, was directed from, and/or emanated from, in whole or in part, this judicial district.

FACTUAL ALLEGATIONS

A. Prof. De Simone and VSL Inc.

26. During the early 1980s and 1990s, Prof. De Simone conducted extensive research into the clinical use of bacterial strains to treat the symptoms associated with various serious diseases, including Inflammatory Bowel Disease ("IBD"), Irritable Bowel Syndrome ("IBS"), Ulcerative Colitis ("UC"), Pouchitis, enteral feeding, and liver disease. Prof. De Simone's work resulted in the synthesis of several therapeutic and dietary formulations containing live bacterial cultures, which are commonly referred to as "probiotics." Prof. De Simone obtained several patents and other intellectual property rights relating to his probiotic formulations in multiple countries, including in the United States. One of Prof. De Simone's probiotic formulations was the eight-strain probiotic mix known as the De Simone Formulation.

27. Prof. De Simone joined forces with the Cavazzas, who controlled one of the largest pharmaceutical conglomerates in Italy. Together, they formed VSL Inc. For a period of time, Prof. De Simone served as its CEO and as a member of its board.

28. Beginning in 2002, after Prof. De Simone decided to license his patent for the De Simone Formulation to VSL Inc., the formulation was launched in the United States under the trademark “VSL#3.” As the relevant patent, and thus the Patent License Agreement, was set to expire on February 9, 2015, the same parties later entered the January 2010 Know-How Agreement to give VSL Inc. a further exclusive license to the De Simone Formulation from the time the patent expired until January 31, 2016.

29. In the years to come, VSL Inc. would sell VSL#3 with great success. Indeed, the De Simone Formulation would become the “gold standard” in its therapeutic class. More than 60 human clinical trials of the De Simone Formulation were successfully completed, and the results of these studies were published in peer-reviewed medical and scientific journals. These trials demonstrated the safety and effectiveness of the De Simone Formulation in the dietary management of, *inter alia*, IBD, IBS, and a very serious and rare chronic disorder called Pouchitis. With respect to Pouchitis, the De Simone Formulation was ultimately recognized by the world’s professional gastroenterology societies as a “standard of care”—an achievement that no other probiotic had previously attained.

30. The De Simone Formulation (as VSL#3) was manufactured by Danisco pursuant to a set of supply agreements. Under the 2008 Danisco Supply Agreement, Prof. De Simone authorized Danisco to use his Know-How consistent with certain confidentiality requirements. The 2014 Danisco Supply Agreement provided that, if the January 2010 Know-How Agreement was

ever terminated, Prof. De Simone would take VSL Inc.'s place as the buyer of Danisco-made VSL#3 (the De Simone Formulation).

B. Prof. De Simone is Forced to Resign from VSL Inc.

31. VSL Inc.'s profits continued to climb, but the Cavazzas sought to increase them further still. The Cavazzas proposed reducing VSL#3's production costs by changing the product's composition and substituting cheaper bacterial strains without informing consumers. Prof. De Simone rejected the idea. Later, in the course of the trial of the District Court Action, it came to light that the Cavazzas had already entered into an agreement with Alfa Wassermann, which promised the VSL#3 product and at a higher profit margin (unbeknownst to the then-current VSL Inc. board of directors). Prof. De Simone refused to violate the trust that consumers had placed in VSL#3. As Prof. De Simone knew, a "fake" formula could easily harm the consumers who depended upon it.

32. In response to Prof. De Simone's unwillingness to assist their efforts, the Cavazzas only increased their pressure. The Cavazzas threatened to sue Prof. De Simone for ownership of the Know-How, although they knew that the Know-How belonged to him. Prof. De Simone had never given up the propriety rights to the formula he had invented. Nonetheless, the Cavazzas insisted: either Prof. De Simone would make a "fake" version of VSL#3 with cheaper ingredients, or they would force him to give up his Know-How, so they could make a fake formula themselves. Prof. De Simone was left with no choice; he resigned from VSL Inc. Prof. De Simone also sought to protect his proprietary information.

33. To that end, in 2015, Prof. De Simone instructed Danisco to cut off VSL Inc.'s access to Danisco-made VSL#3 on a date certain, as was his contractual right. Prof. De Simone also filed suit against VSL Inc. in the United States District Court for the District of Maryland

before Judge Chuang. Prof. De Simone brought various claims against VSL Inc., including a claim for a declaratory judgment that he owned the Know-How. VSL Inc. and Leadiant responded by filing an enormous number of meritless counterclaims, including that VSL Inc. owned the Know-How.

C. ExeGi Accurately Advertises and Sells Visbiome.

34. In 2015, Prof. De Simone granted an exclusive license to market and sell the DeSimone Formulation to ExeGi, a small start-up company. In February 2016, ExeGi began marketing and selling the De Simone Formulation under the name “Visbiome.” The strains of bacteria in Visbiome are now, and have always been, produced from industrial cell banks held by Danisco in Madison, Wisconsin. In April of 2011, for research purposes, ampoules containing isolates of the strains used to make Visbiome by Danisco were deposited at the Leibniz Institute DSMZ-German Collection of Microorganisms and Cell Cultures GmbH (“DSMZ”). DSMZ is a “strain bank” in Braunschweig, Germany that holds various bacterial strains and microorganisms, but not for the purpose of industrial production. Every deposited isolate or strain is given a unique catalog number, referred to as the “DSM” number, which simply corresponds to its account of deposit.³ A few years prior, isolates of the strains used to make Visbiome were also deposited in a United States “strain bank” named ATCC, also for research purposes. Just like with DSMZ, ATCC assigns a catalog number to each deposit, referred to as the “SD” number. As isolates for all eight strains used in the De Simone Formulation are in both the ATCC strain bank and the DSMZ strain bank, each strain has a corresponding SD number and DSM catalog number:

De Simone Formulation Strains	ATCC Code #s	DSMZ Code #s
<i>Lactobacillus acidophilus</i>	SD5212	DSM24735
<i>Lactobacillus plantarum</i>	SD5209	DSM24730

³ A true and correct copy of the DSMZ deposit slips for the Deposited Strains is appended as Exhibit B hereto.

<i>Lactobacillus bulgaricus</i>	SD5219	DSM24734
<i>Lactobacillus paracasei</i>	SD5218	DSM24733
<i>Bifidobacterium breve</i>	SD5206	DSM24732
<i>Bifidobacterium longum</i>	SD5220	DSM24736
<i>Bifidobacterium infantis</i>	SD5219	DSM24737
<i>Streptococcus thermophilus</i>	SD5207	DSM24731

35. The DSM Codes were, and are, public information and scientists frequently used them to describe the De Simone Formulation in their publications. Accordingly, to accurately represent the contents of Visbiome to the public, ExeGi referenced the strains by their DSM Codes on its packaging and packing inserts, as reported in scientific publications. The DSM Codes, just like the ATCC codes, are merely catalog numbers; they are not registered trademarks or any other intellectual property and are publicly available. ExeGi could have just as easily and accurately used the ATCC codes as the DSM Codes; either way, the number is just a reference number that connotes a particular strain that exists in nature (that is industrially produced at Danisco) and is used in the De Simone Formulation.⁴

36. For the purpose of registering the DSMZ isolates consistent with the relevant regulatory requirements in Europe, the Deposited Isolates were deposited in the name of “CD Investments Srl,” which owns 99.97% of VSL Inc. Ex. B. However, as a notation on the deposit slips confirms, the Deposited Isolates can be released only to “Prof C. De Simone.” *Id.* at p. 6.

37. Accordingly, since 2014, Prof. De Simone has paid the yearly invoices for the Deposited Isolates himself. And since 2016, ExeGi has advertised Visbiome, including on its packaging and packaging inserts, as containing: *Lactobacillus paracasei* DSM 24733; *Lactobacillus plantarum* DSM 24730; *Lactobacillus acidophilus* DSM 24735; *Lactobacillus delbruckeii subsp. bulgaricus* DSM 24734; *Bifidobacterium longum* DSM 24735; *Bifidobacterium*

⁴ Notably, in Canada, ExeGi references the ATCC code designations rather than the DSM Codes.

infantis DSM 24736; *Bifidobacterium breve* DSM 24732; and *Streptococcus thermophilus* DSM 24731.

38. In the meantime, while ExeGi advertised Visbiome truthfully, VSL Inc. and its licensees began a campaign of false advertising.

D. Lediand's and Alfagma's False Advertising About VSL Inc.'s Fake Formula.

39. After Prof. De Simone resigned from VSL Inc. and took his Know-How with him, as was his right, VSL Inc. had made good on its threat to manufacture and sell an untested, inferior version of VSL#3: the Fake Formula. VSL Inc. and its licensees sold the Fake Formula, which was materially different from the De Simone Formulation (including, but not limited to, the fact that it had different strains, in different proportions, and was manufactured in a different way), under the VSL#3 trademark. But they never informed consumers that VSL#3's formulation had changed.

40. To the contrary, Lediand and Alfagma falsely advertised the Fake Formula as "the same" as, and equivalently efficacious to, the De Simone Formulation. In their advertisements, Lediand and Alfagma usurped the scientific and clinical history of the De Simone Formulation and presented it as that of the Fake Formula. They falsely claimed that the Fake Formula had a fifteen-year clinical history and falsely cited the studies that had been conducted on the De Simone Formulation as their own.

41. By way of example only, Lediand issued advertisements falsely stating that VSL#3 was "the same quality product containing the same genus and species of bacteria in the same proportions that you have come to expect" and asserting: "How will this impact you and your patients? It won't." Lediand also falsely advertised the Fake Formula as containing the "same proportions" as the De Simone Formulation, although it did not.

42. For its part, Alfasigma advertised the Fake Formula as “maintaining the original proprietary mix of eight strains of live bacteria,” even though the Fake Formula had only seven strains, and Alfasigma had no access to, or knowledge of, Prof. De Simone’s “original proprietary mix.” Alfasigma also falsely advertised the Fake Formula as being backed by “170 published clinical studies and reviews,” “in which all efficacy and safety data yielded stellar results.” These clinical studies had all been conducted on the De Simone Formulation, and Alfasigma had never conducted any efficacy testing on the Fake Formula at all. Neither had Leadiant or VSL Inc. Alfasigma even falsely stated that the new manufacturing plant for the Fake Formula had produced VSL#3 until 2006 and was simply resuming its manufacturing of that product in 2016, when it had, in fact, never produced commercially available VSL#3. Together, they intentionally misled consumers, some of them gravely ill, on issues concerning the consumers’ health.

E. The District Court Action.

43. Upon discovering these falsities, ExeGi joined the District Court Action and brought claims against Leadiant and Alfasigma for false advertising under the Lanham Act. In response, Alfasigma filed a series of counterclaims against both ExeGi and Prof. De Simone. Including those claims, in total, the District Court Defendants asserted a whopping 52 counterclaims against Prof. De Simone and/or ExeGi.

44. VSL Inc. brought a counterclaim against Prof. De Simone that put the ownership of the Know-How, including the Deposited Isolates, directly at issue. More specifically, VSL Inc. alleged that Prof. De Simone had breached his fiduciary duty to VSL Inc. by “taking” the Know-How, which VSL Inc. claimed was a protectable “trade secret”—and its property. In its counterclaims, VSL Inc. defined “Know-How” to include: “technical and non-technical information, discoveries, improvements, processes, formula, data, inventions, *biological*

materials, and other information which is useful or necessary to have made, develop, use, or sell VSL#3.” (emphasis added).

45. VSL Inc. also alleged that Prof. De Simone had breached his fiduciary duty by “secretly” inserting the provision into the 2014 Danisco Supply Agreement that provided that, if the 2010 Know-How Agreement was terminated, Prof. De Simone would take VSL Inc.’s place as the sole buyer of Danisco-produced VSL#3.

46. Further, VSL Inc., Ladiant and Alfasigma each brought a counterclaim under the Lanham Act for both false advertising and unfair competition against Prof. De Simone and ExeGi. The District Court Defendants challenged various statements in ExeGi’s marketing and advertising materials—and certain aspects of ExeGi’s packaging and packaging inserts—as false, misleading or otherwise unfair. Yet, the District Court Defendants never contested ExeGi’s right to reference the DSM Codes, which had appeared on ExeGi’s packaging since the inception of Visbiome. In fact, on page 64 of VSL Inc.’s operative complaint in the District Court Action (VSL Inc.’s Second Amended Answer and Counterclaim (“VSL Inc.’s SAC”)), VSL Inc. included a picture of the “Visbiome Product Packaging” and specifically listed the issues it took with that packaging as part of stating its Lanham Act claims. The DSM codes are clearly visible on the side of the Visbiome box in that picture:



Notably, by the time VSL Inc.’s SAC was filed, VSL Inc. had already asserted ownership over the Know-How (including “biological materials”) and Actial had already made the claim in the Court of Rome that it owned the Deposited Isolates. However, **VSL Inc. did not ever allege, in the SAC or any other filing throughout the whole litigation**, that there was anything false, misleading, or unfair about ExeGi’s use of the DSM codes in the District Court Action; neither Leadiant nor Alfasigma did either.

47. On October 9, 2018, the Court resolved the parties’ pending motions for summary judgment. In his Memorandum Opinion, Judge Chuang was clear: “De Simone owns the Know-

How.” Having declared Prof. De Simone “the owner of the Know-How,” Judge Chuang also noted that VSL Inc., “anticipating the Court’s ruling as to ownership of the Know-How,” had “sought to re-formulate the question and argue that it should prevail on the Know-How claims because the Know-How was not, and is no longer, a trade secret.” Judge Chuang had no trouble apprehending “the obvious fact that this argument [wa]s squarely contradicted by VSL’s assertion in its pleadings that the Know-How is a trade secret and its allegation that De Simone has misappropriated a trade secret by using the Know-How.” Beyond that, as Judge Chuang noted, VSL Inc.’s “eleventh-hour assertion” lacked any evidentiary support. Either way, because Prof. De Simone could not “be held liable for misappropriating intellectual property that he rightfully owned,” Judge Chuang dismissed a large portion of VSL Inc.’s claim for breach of fiduciary duty with prejudice.

48. Judge Chuang declined to grant summary judgment for either party on the remainder of VSL Inc.’s breach of fiduciary duty claim. As Judge Chuang observed, VSL Inc.’s evidence was contradicted by evidence offered by ExeGi and Prof. De Simone. More specifically, witness testimony and documents demonstrated that Prof. De Simone was inserted into the 2014 Agreement solely due to Danisco’s concerns about liability. Since VSL Inc. was not inclined to assume the risk, Prof. De Simone had offered to assume the liability himself. The Court noted that the witness testimony had support in the 2014 Danisco Supply Agreement itself. Even so, the Court found that “genuine issues of material fact” remained as to “whether De Simone breached his fiduciary duty by executing the 2014 Danisco Supply Agreement.” As the Court held: “this question needs to be resolved by a finder of fact.” Accordingly, VSL Inc.’s claim for Prof. De Simone’s breach of fiduciary duty “based on the 2014 Danisco Supply Agreement” would be “resolved at trial.”

49. On October 30, 2018, the trial commenced. It would last for three weeks. Throughout the trial, VSL Inc. continued pressing its argument before the jury that Prof. De Simone did not own the Know-How, although Judge Chuang had already determined otherwise. VSL Inc. also offered the testimony of numerous witness to support its position that there could be no such thing as intellectual property rights in bacterial strains, since bacterial strains are found in nature. Still, VSL Inc. attempted to persuade the jury that Prof. De Simone had breached his fiduciary duty by “taking” the Deposited Isolates for himself when, according to VSL Inc., the Deposited Isolates belonged to it.

50. Ultimately, the jury rejected VSL Inc.’s arguments, and its “evidence,” in their entirety. In doing so, the jury considered, among other things, the strain bank deposit slips, including the notation confirming that the Deposited Isolates could be released solely to “Prof. C. De Simone.” The jury also considered Prof. De Simone’s un rebutted testimony confirming that the Deposited Isolates could be released only to him.

51. On November 20, 2018, the jury reached a unanimous verdict in favor of Prof. De Simone and ExeGi and against the District Court Defendants. The jury conclusively determined that Prof. De Simone had not breached his fiduciary duty to VSL Inc. In addition, the jury found that VSL Inc. was liable to Prof. De Simone for breach of contract and unjust enrichment, Leadiant was liable to Prof. De Simone for unjust enrichment, and Leadiant and Alfasigma were both liable to ExeGi for their false advertising. Together, Prof. De Simone and ExeGi were awarded \$18,014,041 in damages.

52. The jury did not determine whether ExeGi had engaged in false advertising and unfair competition under the Lanham Act, because the question was no longer before the jury. The

District Court Defendants had voluntarily dismissed their Lanham Act claims themselves, with prejudice.

53. The Court entered a final judgment on the verdict on November 21, 2018. In doing so, the Court held: “Any and all prior rulings made by the Court disposing of any claims against any parties are incorporated by reference herein.”

54. The District Court Defendants subsequently filed post-trial motions for judgment as a matter of law and a new trial. ExeGi filed a motion for a permanent injunction. On June 21, 2019, this Court denied the District Court Defendants’ post-trial motions in their entirety and granted in part ExeGi’s motion for a permanent injunction. The Court permanently enjoined Alfasigma and Leadiant from: (1) stating or suggesting in VSL#3 promotional materials that the present version of VSL#3 contains the same formulation found in the De Simone Formulation, including by making statements that VSL#3 contains the “original proprietary blend” or the “same mix in the same proportions” as the earlier version of VSL#3; and (2) citing to or referring to any clinical studies performed on the De Simone Formulation or earlier versions of VSL#3 as relevant or applicable to the current formulation of VSL#3.

F. VSL Inc.’s Unfair Competition and Tortious Interference with ExeGi’s Business Relationships.

55. Despite Judge Chuang’s determination in October of 2018 that Prof. De Simone owned the Know-How, which VSL Inc. had itself defined to embrace any and all “information” “useful or necessary” to make the De Simone Formulation, including “biological materials,” VSL Inc. and Actial continued to argue that they “owned” the Deposited Isolates in the DSMZ accounts before the Court of Rome. In the meantime, the DSMZ continued to send Prof. De Simone invoices for the Deposited Isolates (and Prof. De Simone continued to pay them), because they belong to him.

56. On July 26, 2019, the Court of Rome published a preliminary determination that the transfer of title of the ampoules containing the Deposited Isolates in the name Prof. De Simone was “invalid and must be annulled” and, thus, the ampoules would be “returned at the request of the company succeeding CD Investments Srl.” Ex. C at 26. However, the Court of Rome rejected Actial’s claim for compensation for any resulting losses. *Id.* Other than ordering Prof. De Simone to pay his half of the proceeding’s costs (approximately €14,000, with Actial paying the other half), those two findings were the only conclusions determined by the Court of Rome. *See* Ex. C at 18-28.

57. However, VSL Inc. and Alfasigma had been hemorrhaging customers since the jury reached its verdict in the District Court Action. As many consumers of VSL#3 learned about their false advertising, they abandoned the fake product for Visbiome – the real De Simone Formulation that they thought they were buying when they purchased the falsely-advertised version of VSL#3. That problem was compounded by the fact that VSL Inc. and Alfasigma refused to remove the false advertising from VSL#3’s packaging, package insert, and other advertising material. Most distributors, wholesalers and resellers, concerned with the moral, business, and legal repercussions of participating in VSL Inc. and Alfasigma’s now well-known false advertising scheme, ceased selling VSL#3 entirely.

58. In order to stem the losses of all of its customers, VSL Inc. decided to jump on the preliminary decision of the Court of Rome and see if could use it in any way possible to regain its now-evaporated market share from ExeGi. Thus, on August 5, 2019, VSL Inc., through counsel, wrote to Danisco’s counsel, purportedly to advise Danisco of the Court of Rome’s decision.⁵ In

⁵ A true and correct copy of VSL Inc.’s August 5, 2019 letter (the “Danisco Letter”) is appended as Exhibit C hereto.

the Danisco Letter, VSL Inc. confirmed that it knew that Danisco manufactured Visbiome “pursuant to agreements” with ExeGi and Prof. De Simone. Ex. C at 1. VSL Inc. then “advise[d]” Danisco that the Court of Rome recently “concluded that the eight DSM codes that are prominently displayed on Visbiome® packaging and package inserts, and the eight specific bacterial strains contained in those DSMZ accounts, belong to VSL’s parent company, Actial Farmaceutica S.r.l. (“Actial”), and not to De Simone.” This statement is an outright falsity. VSL Inc. and Brian Schwalb, VSL Inc.’s counsel who sent the letter to Danisco, surely knew it was false, as he attached a copy of the Court of Rome’s decision that he purported to summarize in both Italian (Exhibit A to the Danisco Letter) and translated to English (Exhibit B to the Danisco Letter). A review of that decision shows beyond any doubt that the Court of Rome *did not determine that the eight DSM codes belong to Actial; in fact, the question of ownership of the codes was never posed to, nor considered by, the Court of Rome.* As noted above, the Court of Rome’s conclusion was limited to Actial owning the ampoules containing the Deposited Isolates filed at the DSMZ and offer no opinion on ownership or intellectual property rights of the DSM Codes themselves or even what it is inside the ampoules.

59. VSL Inc.’s intentionally false misrepresentation that the Court of Rome determined that the eight DSM Codes “belong to” Actial was not a trivial mistake. Rather, it forms the basis for VSL Inc.’s demand of Danisco that, as a result of the Court of Rome’s decision, “steps must be taken immediately to cease and desist from the production, distribution and sale of Visbiome unless and until any reference to the DSM [Codes] is removed from its packaging and packaging inserts” and from “any marketing and reference materials for Visbiome.” *Id.*

60. In its Danisco Letter, VSL Inc. also demanded that Danisco “immediately cease any further production or delivery of the Visbiome product to ExeGi” unless and until VSL Inc.

received “confirmation that such product will not be marketed, distributed or sold with any reference to the DSM codes.” Ex. C at 3. VSL Inc. further demanded that Danisco “immediately cease” assisting “any third party engaged in packaging, distributing or selling” Visbiome “with reference to the DSM codes” and “immediately recall all Visbiome product containing or otherwise referring to the DSM codes.” *Id.* According to VSL Inc., any use of the DSM Codes was false and misleading, and it would amount to “false advertising” and a “misappropriation of property rights that belong to Actial.” *Id.* at 2-3. Suddenly, according to VSL Inc., the property rights that it had previously argued were nonexistent were now “valuable.” *Id.* at 2.

61. VSL Inc.’s position is non-sensical; it is clearly made without a legal basis and solely for the purpose of interfering with ExeGi’s business relationships. The DSM Codes are merely a catalog number; even if Actial were the rightful owner of the ampoules containing the Deposited Isolates (which it is not), that would not make ExeGi’s use of the DSM Codes wrongful or false in any way. The DSM Codes themselves are assigned by DSMZ; certainly, neither Actial nor VSL Inc. can claim a property right over the public code number, particularly one which they had no role in generating. Notably, when alerted of this ridiculous “controversy,” DSMZ’s counsel took no issue whatsoever with ExeGi’s use of the DSM Codes on its box; the DSM Codes are also publicly available and free to use.

62. In fact, VSL Inc.’s current position is directly contrary to the position it took in its First Amended Consolidated Notice of Opposition (“Notice of Opposition”) in an action in the United States Patent and Trademark Office Before the Trademark Trial and Appeal Board.⁶

63. In that action, VSL Inc. opposed Mendes SA’s application to get a trademark for the names of the eight strains found in the De Simone Formulation, where each proposed mark

⁶ A true and correct copy of the Notice of Opposition is appended as Exhibit D hereto.

incorporated the DSM number. For example, Mendes SA had applied for a trademark for “Lactobacillus Acidophilus DSM24735” and “Bifidobacterium breve DSM24732,” as well as the six other strain names. These eight strain names are exactly what appears on Visbiome’s box and exactly what VSL Inc. was now contesting in the Danisco Letter. However, VSL Inc. did not contest those marks on the basis that it owned the DSM Codes or on the basis that it had rights to the Deposited Isolates. Far from it. Rather, VSL Inc. took the following position, which is directly contrary to the position it took in the Danisco Letter:

All of the marks set forth in the Bacterial Strain Applications incorporate specific scientific strain designations that begin with the letter string “DSM” and are followed by a five-digit number (“DSM Strain Designations”).

DSM Strain Designations identify specific bacterial strains catalogued by DSMZ, or Leibniz Institute DSMZ-Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH, one of the largest biological resource centers worldwide, located in Braunschweig, Germany: <https://www.dsmz.de/home.html> (“DSMZ”).

The DSM Strain Designations are used by the scientific community to identify specific cultivated varieties or subspecies of bacterial strains.

The marks set forth in the Bacterial Strain Applications *are generic and the common descriptive names of bacteria, by which such bacteria are known to the U.S. consumer.*

Ex. D, at 5 (Emphasis added). VSL Inc. continued: “the DSM Strain Designations identify strains catalogued by DSMZ and [] the DSM Strain Designations are used by the scientific community to identify specific cultivated varieties or subspecies of bacterial strains.” Ex. D, at 6-7.

64. Amazingly, VSL Inc. even went so far as to argue to the Trademark Trial and Appeal Board that trademark applications should be denied because VSL Inc. “has an interest in using the bacterial strain designations identified in the Bacterial Strain Applications descriptively in its business, including, without limitation, to identify ingredients within [VSL Inc.’s] Products” and that “[VSL Inc.] will be harmed if it is not permitted to use the marks identified in the Bacterial Strain Applications descriptively in its business, including without limitation, to accurately

identify the strains that comprise [VSL Inc.'s] Products.” Ex. D, at 4-5. Yet, now, VSL Inc. is attempting to deny the same right of merely accurately describing the contents of its product to ExeGi. Further, it is telling Danisco and other wholesalers and distributors of Visbiome that the product cannot be sold if it contains these DSM Codes, despite earlier representations to the court that those codes are generic, merely descriptive names used by the scientific community to identify these strains. VSL Inc.'s previous representations to the Trademark Trial and Appeal Board demonstrate that its current attack on ExeGi's business and business relationships is an intentional, willful wrongdoing, without any substantial justification, as VSL Inc. knows that it has no proprietary right over the DSM Codes.

65. VSL Inc. prevailed on this issue with the Trademark Trial and Appeal Board and successfully blocked Mendes SA's trademark application. Thus, the doctrine of judicial estoppel will also prevent VSL Inc. from pursuing the legal recourse that it threatens in the Danisco Letter, as it requires VSL Inc. to take a contrary position to that upon which it already prevailed. Pursuant to judicial estoppel, where a litigant assumes a certain position in a legal proceeding, and succeeds in maintaining that position, it may not thereafter, simply because its interests have changed, assume a contrary position.

66. Furthermore, there is no dispute that the strains referenced by the DSM numbers are actually in Visbiome. Even if Actial or VSL Inc. were to own the Deposited Isolates, that would not make the reference to the DSM Codes on the Visbiome box false in any way. Danisco holds the original strains from which the Deposited Isolates were harvested, and there is no dispute that Danisco, in fact, uses those original strains in making Visbiome. Nor can VSL Inc. attempt to somehow take possession of the original strains via an assertion of ownership of the Deposited Isolates. VSL Inc. introduced testimony at trial, including from Danisco's own corporate

representative, that strains are commonly occurring in nature and cannot be owned. While a particular copy of a strain may be owned by a depositor, that does not mean the owner of that copy is entitled to block everyone else from using the original strain, other copies, or identical strains. Yet, VSL Inc. asserts that its potential ownership of the Deposited Isolates somehow entitles it to ownership of the original strain at Danisco, a position that has no legal support and does not make any logical sense.

67. An analogy is useful to show the absurdity of VSL Inc.'s "demand." In the District Court Action, numerous witnesses explained to the jury that a strain number is simply a way of identifying an individual bacterial strain, just like a name describes a person. So "*Lactobacillus paracasei* DSM 24733" is akin to a name, Yamil Hernandez, for example. Just as with a name, the strain number is not the physical object itself, it is merely a name to describe a particular live organism. The analogous situation to VSL Inc.'s position would be if stem cells were collected at birth for a baby and saved in a stem cell bank, which saved them under the name by which the world calls that baby - Yamil Hernandez (for a true analogy, the stem cell bank would be the generator of that name, but that is of no consequence to the impropriety of VSL Inc.'s position). A fight ensues between two third parties over who owns the stem cells in the cell bank, and then the (preliminary) winner of that fight goes out and asserts that ExeGi can no longer put on its website that Yamil Hernandez works at ExeGi because the winner now owns Mr. Hernandez due to its ownership of the stem cells. It sounds absurd, but that is only because VSL Inc.'s position is absurd. Just as (1) no one can own Yamil Hernandez, the person; (2) ownership of a stem cell sample would not confer ownership over the person from which it was taken; and (3) it is not false for ExeGi to promote the fact that Mr. Hernandez works at ExeGi, regardless of who owns the stem cells, it is equally true that (1) no one can own the bacterial strain known as *Lactobacillus*

paracasei DSM 24733; (2) ownership of the Deposited Isolate would not confer ownership over the strain from which it was taken; and (3) it is certainly not false for ExeGi (or Danisco, or any other reseller) to promote the presence of *Lactobacillus paracasei* DSM 24733 in Visbiome, regardless of who owns the Deposited Isolates, when that is indisputably the case.

68. VSL Inc.’s position is even further undermined by the fact that the ruling in the Court of Rome is not final and is not executable. According to Italian Law, the Court of Rome’s finding is merely a “declarative decision,” which means that it will be executable only when (and if) it is confirmed by the Court of Appeal and (eventually) the Supreme Court of Italy (see art.282 of the Italian Civil Procedure; Court of Cassation United Civil Sections 22/2/2010 n.4059; Court of Cassation Section 2, 26/3/2009, No. 7369; Court of Cassation Section 3, 20/2/2018; Court of Cassation Section 1, 6/2/1999 No. 1037; Court of Cassation Section 2, 12/7/2000 No. 9236). Additionally, according to art.324 of the Italian Civil Procedure Code, the declarative decision “is considered final when it is no longer subject to jurisdiction regulation, appeal or cassation (*i.e.* the Italian Supreme Court) or revocation. This means, without any doubt, that the Court of Rome’s declarative decision is only a step in the proceedings, which cannot be enforced by anyone, much less VSL Inc., which is not even a party to the proceedings.

69. Further, even if it was a final and executable judgment in Italy, which it will not be for many years, if ever, it would still not be binding upon DSMZ, which is a German company. DSMZ has already confirmed in writing that it will not transfer the Deposited Isolates to Actial unless and until there is a final ruling that is nationalized in Germany (and thus would finally be binding on DSMZ).⁷ But, again, even if DSMZ were to turn the Deposited Isolates over to Actial

⁷ On August 11, 2019, Corporate Counsel for the DSMZ wrote to counsel for Prof. De Simone to confirm that the DSMZ would continue to keep the Deposited Isolates “in their current status.” That is, the DSMZ is continuing to keep the Deposited Isolates in Prof. De Simone’s name and

or VSL Inc., there would be no impact on the legality of the marketing of Visbiome or use of the DSM references, as it would mean nothing more than who has custody of a physical ampoule containing an isolate of a certain strain. There is no doubt that ExeGi still would have every legal right to reference the strains found in Visbiome using the catalog numbers used by DSMZ.

70. VSL Inc.'s position is additionally without justification because it is precluded by the doctrines of *res judicata* and collateral estoppel, as is well known by VSL Inc.'s counsel, the author of the Danisco Letter. VSL Inc. already brought false advertising and unfair competition claims against ExeGi for packaging and advertisements that contained these same DSM Codes (as seen in VSL Inc.'s SAC). Despite maintaining and developing those claims for years, and even moving for summary judgment on those claims, none of the District Court Defendants ever alleged that ExeGi's use of the DSM Codes was a violation of the Lanham Act (or an issue for any other reason). The District Court Defendants voluntarily dismissed all of their Lanham Act claims with prejudice years after bringing those claims, during the third week of trial in the District Court Action, and *res judicata* prevents VSL Inc. from bringing a new claim now based on the same advertising that was the subject of already completed litigation.

71. Collateral estoppel also prevents VSL Inc. from asserting these claims. As noted above, VSL Inc. already asserted ownership over the biological materials (i.e., the bacterial strains) used to make the De Simone Formulation in seeking a declaratory judgment that it owned the Know-How. This claim was rejected by Judge Chuang in his summary judgment decision and cannot be relitigated now. Additionally, at trial, the author of the Danisco Letter himself, Mr.

possession, which makes sense. The preliminary finding in the Court of Rome is not final, not executable, and not binding on the DSMZ in any case. As DSMZ has always understood that Prof. De Simone was the owner of the Deposited Isolates, it has refused to waiver and declined to turn the Isolates over to Actial.

Schwalb, heavily pursued the theory that Prof. De Simone had wrongfully transferred the Deposited Isolates to himself as part of VSL Inc.'s claim for breach of fiduciary duty. That claim was rejected by the jury, which found that Prof. De Simone did not breach his fiduciary duty to VSL Inc. in any respect whatsoever. Again, collateral estoppel would prevent VSL Inc. from reasserting this same position in a new case, as Mr. Schwalb is keenly aware. That is yet another reason that the threats made in the Danisco Letter and the letters referenced below are tortious and without legal justification.

72. Despite all of the above reasons that the positions taken by VSL Inc. in the Danisco Letter were totally unjustifiable, were without merit, and were taken simply to harm ExeGi and to benefit VSL Inc., VSL Inc.'s attempt to parlay the Court of Rome decision into a recapture of market share went far beyond the Danisco Letter. On August 8, 2019, Actial and VSL Inc., through counsel, sent a similar letter to Orphan SA Pharmaceuticals (Pty) Ltd. ("Orphan").⁸ Orphan distributes the De Simone Formulation in South Africa, where it is branded and sold under the name "Vivomixx." *See* Ex. E.

73. In its August 8 letter, Actial and VSL Inc. repeated their failed allegations that Prof. De Simone had breached his fiduciary duties to VSL Inc.; this time, more directly. According to Actial and VSL Inc., "while serving in a fiduciary capacity" to VSL Inc., Prof. De Simone had "carefully orchestrated his departure from VSL Group [by], among other things[,] plotting to interfere with the continuing supply of VSL#3 from Actial." Ex. E at 2. Actial and VSL Inc. insisted: "in breach of his fiduciary duties," Prof. De Simone had misappropriated the Deposited Isolates, which the Court of Rome had determined belonged to Actial. *Id.* Once again, Actial and VSL Inc. contended that "any use" of "the DSM Codes" by Prof. De Simone or Orphan would

⁸ A true and correct copy of the August 8, 2019 letter is appended as Exhibit E hereto.

“amount to a misappropriation of the DSM Codes” and “an act of unfair competition” and “infringement.” *Id.* at 3. They ordered Orphan to “immediately discontinue” any reference to the DSM Codes in conjunction with the sale or distribution of Vivomixx and to “immediately recall all the batches of Vivomixx” with “any reference to the DSM Codes.” *Id.* at 3-4. For all of the reasons stated above, these positions were entirely unjustifiable and without merit. Similar letters were sent to distributors of the De Simone Formulation around the world.

74. On August 9, 2019, VSL Inc.’s counsel sent a letter directly to counsel for ExeGi and Prof. De Simone with similar “cease and desist” demands.⁹ VSL Inc. also repeated its contention that the DSM Codes embraced “valuable property rights,” and maintained that any use of the DSM Codes in connection with marketing or advertising Visbiome constituted “false advertising” and “unfair competition.” Ex. F at 2. According to VSL Inc., ExeGi’s references to the DSM Codes had also “resulted in De Simone and ExeGi being unjustly enriched.” *Id.* Given that ExeGi and Prof. De Simone’s counsel knew that VSL Inc.’s claim for breach of fiduciary duty had failed, having successfully defended against it, VSL Inc.’s counsel opted against reasserting its allegations that Prof. De Simone had breached his fiduciary duty. But that did not stop him from demanding that ExeGi cease all sales of Visbiome (and recall outstanding inventory) based on the absurd, unjustifiable positions stated above.

75. On August 13, 2019, VSL Inc.’s counsel sent a letter to Pharma Holding, Inc. (d/b/a/ Unzer Pharmacy) (“Pharma Holding”). Pharma Holding is an authorized reseller of Visbiome on Amazon, meaning ExeGi has a contractual agreement with Pharma Holding that allows Pharma Holding to market and sell Visbiome on Amazon. Once again, VSL Inc. repeated

⁹ A true and correct copy of the August 9, 2019 letter is appended as Exhibit F hereto.

the falsities it stated to Danisco in the Danisco Letter and, as with the other letters, insisted that, “[a]ccordingly, steps must be taken immediately to cease and desist from the distribution and sale of Visbiome® unless and until any reference to the DSM accounts is removed from its packaging and packaging inserts as well as from any marketing or reference materials for Visbiome®.” (Emphasis in original.)

76. Upon information and belief, VSL Inc.’s counsel has sent nearly identical letters to numerous other authorized resellers of Visbiome, who also have a contractual agreement with ExeGi that allows the reseller to market and sell Visbiome on Amazon and various other platforms. Each of these letters presents a completely unjustified attempt by VSL Inc. to unfairly compete with ExeGi through fraud, deceit, trickery and other unfair methods as well as to interfere with ExeGi’s business relationships. Upon information and belief, VSL Inc.’s plan to harm ExeGi has achieved some measure of success as it has resulted in lost sales due to buyers that were scared and confused by VSL Inc.’s threats.

COUNT I
Declaratory Judgment Pursuant to 28 U.S.C. § 2201

77. ExeGi adopts by reference each and every one of the foregoing factual allegations as if alleged in full in Count I, except as they may be inconsistent with the specific allegations contained in Count I.

78. By virtue of the letters that VSL Inc. sent to Danisco’s counsel, to ExeGi’s counsel, and to other resellers of Visbiome, VSL Inc. is contesting and denying ExeGi’s rights to continue referencing the DSM Codes in conjunction with its marketing, advertising, and sale of Visbiome. Beyond that, VSL Inc. has ordered ExeGi and Danisco to “immediately” “cease and desist from the production, distribution and sale of Visbiome unless and until any reference to the DSM [Codes] is removed from its packaging and packaging inserts” and from “any marketing and

reference materials for Visbiome.” VSL Inc. has also demanded that ExeGi and Danisco “immediately recall all Visbiome product containing or otherwise referring to the DSM codes.” Further, in its letters, VSL Inc. has contended that any use of or reference to the DSM Codes by ExeGi or Danisco in conjunction with Visbiome is false or misleading and amounts to “false advertising” and “unfair competition.”

79. In light of the above facts, there is an actual and justiciable controversy of sufficient immediacy and reality between VSL Inc. and ExeGi over ExeGi’s right to reference the DSM Codes in conjunction with its marketing, advertising, and sale of Visbiome, and whether any such references amount to false advertising or unfair competition under the Lanham Act.

80. As alleged herein, this Court possesses an independent basis for subject-matter jurisdiction over the parties, as there is total diversity of citizenship and the amount in controversy exceeds \$75,000.00, and this dispute concerns a federal question under the Lanham Act.

81. Issuance of the declaratory judgment prayed for herein will serve a useful purpose in clarifying and settling ExeGi’s right to reference the DSM Codes in conjunction with its marketing, advertising, and sale of Visbiome, and it will afford relief from the uncertainty, insecurity, and controversy giving rise to this proceeding. Such uncertainty, insecurity, and controversy has already arisen because of the positions taken by VSL Inc., which ExeGi vigorously contests.

COUNT II
Tortious Interference with Business Relationship

82. ExeGi adopts by reference each and every one of the foregoing factual allegations as if alleged in full in Count II, except as they may be inconsistent with the specific allegations contained in Count II.

83. ExeGi has a business relationship with Danisco, as evidenced by, among other things, the valid and enforceable contract between ExeGi and Danisco that is not terminable at will.

84. VSL Inc. knew of the contractual and business relationship between ExeGi and Danisco, as reflected in the letter from VSL Inc. to Danisco dated August 5, 2019.

85. VSL Inc. intentionally and willfully sought to damage ExeGi (and benefit itself at the expense of ExeGi) by wrongfully interfering with this relationship in order to eradicate ExeGi's supply of Visbiome to sell to consumers by demanding, in the Danisco Letter, that Danisco: "immediately cease" any further production or delivery of the Visbiome product to ExeGi" unless and until VSL Inc. received "confirmation that such product will not be marketed, distributed or sold with any reference to the DSM codes"; "immediately cease" assisting "any third party engaged in packaging, distributing or selling" Visbiome "with reference to the DSM codes"; and "immediately recall all Visbiome product containing or otherwise referring to the DSM codes." As VSL Inc. was well aware when it made these baseless demands of Danisco, if Danisco complied with these demands, ExeGi would have no Visbiome to sell to consumers, as Danisco is the sole manufacturer of all Visbiome.

86. ExeGi also has a business relationship with Pharma Holding and other resellers, as evidenced by, among other things, the valid and enforceable contract between ExeGi and Pharma Holding and ExeGi and the other resellers.

87. VSL Inc. intentionally and willfully sought to damage ExeGi (and benefit itself at the expense of ExeGi) by wrongfully interfering with these relationships in order to reduce the resellers', such as Pharma Holding's, sales of Visbiome. VSL Inc. did so by demanding that the resellers "immediately [] cease and desist from the distribution and sale of Visbiome® unless and

until any reference to the DSM accounts is removed from its packaging and packaging inserts as well as from any marketing or reference materials for Visbiome®.”

88. VSL Inc. took its actions intentionally, with unlawful purpose, without right, and with unjustifiable cause. VSL Inc.’s Danisco Letter, and the subsequent letters mentioned above, contained false information about the Court of Rome’s findings, injurious falsehoods about Prof. De Simone, and the implicit threat of a civil suit against Danisco, ExeGi, distributors, wholesalers and resellers, should any of them fail to comply with VSL Inc.’s “cease and desist demands,” although VSL Inc. knew that such a suit would be groundless.

89. Upon information and belief, VSL Inc. has published and continues to publish the same or similar false and injurious statements and litigation threats to other business relations of ExeGi, as well as to anyone in the general public who many have access to such statements.

90. As a direct and proximate cause of VSL Inc.’s actions, ExeGi has suffered damages, including, but not limited to, being forced to expend substantial resources to combat VSL Inc.’s false accusations in its letter to Danisco and lost sales.

91. In addition, for the reasons set forth herein, ExeGi requests that the Court issue a preliminary and permanent injunction preventing VSL Inc. from taking any action to interfere with ExeGi’s contractual and business relationships.

92. Absent this injunction, ExeGi will suffer immediate, substantial, and irreparable harm to its business, including the loss of current and future ExeGi customers and business relationships.

93. Any remedies available at law, including monetary damages, are inadequate to compensate ExeGi for its injury.

94. The equities support ExeGi's requested relief, as the harm to ExeGi by not entering the injunction is significant and outweighs any harm to VSL Inc. by entering the injunction.

95. Considering the balance of hardships between ExeGi and VSL Inc., which tip in ExeGi's favor, a remedy in equity is warranted.

96. Granting the injunction is in the public's interest, as it is in the public's interest to maintain the status quo, protect the sanctity of contracts, and ensure consumers' continued access to medical products.

97. In addition, VSL Inc. is also liable for, and ExeGi is entitled to recover, punitive damages and attorneys' fees in an amount exceeding \$75,000 because VSL Inc. engaged in the above-described conduct willfully, maliciously, with the intent to damage ExeGi, and without justifiable cause.

COUNT III
Common Law Unfair Competition

98. ExeGi adopts by reference each and every one of the foregoing factual allegations as if alleged in full in Count III, except as they may be inconsistent with the specific allegations contained in Count III.

99. VSL Inc. engaged in fraud, deceit, trickery, and/or unfair methods by sending the aforementioned letters to Danisco and ExeGi's wholesalers and distributors.

100. For the reasons set forth above, such letters contained numerous misrepresentations and took a clearly unsupportable position that all Visbiome, ExeGi's sole product, would need to be recalled and the packaging changed due to an entirely fictitious violation of VSL Inc.'s rights. VSL Inc. made threats of litigation that it knew to be groundless, maliciously, in bad faith and solely to harm ExeGi and its critical business relationships, and without justifiable cause.

101. VSL Inc.'s aforementioned letters constitute an intentional act to jeopardize and to damage ExeGi's business by fraud, deceit, trickery, and other unfair methods.

102. As a direct and proximate result of VSL Inc.'s acts alleged herein, ExeGi has been damaged or jeopardized, including that ExeGi itself, as well as ExeGi's supplier, distributors, wholesalers, and other business partners have lost sales and have been threatened to cease supplying or selling Visbiome under threat of litigation.

103. By reason of the foregoing, ExeGi has suffered compensatory damages in an amount exceeding \$75,000.

104. In addition, for the reasons set forth herein, ExeGi requests that the Court issue a preliminary and permanent injunction preventing VSL Inc. from continuing to unfairly compete with ExeGi.

105. Absent this injunction, ExeGi will suffer immediate, substantial, and irreparable harm to its business, including the loss of current and future ExeGi customers and business relationships.

106. Any remedies available at law, including monetary damages, are inadequate to compensate ExeGi for its injury.

107. The equities support ExeGi's requested relief, as the harm to ExeGi by not entering the injunction is significant and outweighs any harm to VSL Inc. by entering the injunction.

108. Considering the balance of hardships between ExeGi and VSL Inc., which tip in ExeGi's favor, a remedy in equity is warranted.

109. Granting the injunction is in the public's interest, as it is in the public's interest to ensure consumers' continued access to medical products and to prevent unfair business competition.

110. In addition, VSL Inc. is also liable for, and ExeGi is entitled to recover, punitive damages in an amount exceeding \$75,000 because VSL Inc. engaged in the above-described conduct willfully, maliciously, with the intent to damage ExeGi, and without justifiable cause.

PRAYER FOR RELIEF

WHEREFORE, ExeGi demands judgment against VSL Inc. and respectfully seeks:

(a) A declaration that:

i. ExeGi has the right to reference the DSM Codes in conjunction with the marketing, advertising, and sale of Visbiome;

and

ii. ExeGi's references to the DSM Codes in conjunction with its marketing, advertising, and sale of Visbiome do not constitute false advertising or unfair competition under the Lanham Act.

(b) Judgment for ExeGi and against VSL Inc. for VSL Inc.'s tortious interference with ExeGi's contractual and business relationships in an amount to be proven at trial, as well as punitive damages and attorneys' fees, in an amount in excess of \$75,000;

(c) Judgment for ExeGi and against VSL Inc. for VSL Inc.'s unfair competition with ExeGi in an amount to be proven at trial, as well as punitive damages and attorneys' fees, in an amount in excess of \$75,000;

(d) Preliminary and permanent injunctive relief against VSL Inc. preventing VSL Inc. from taking any action to unfairly compete with ExeGi or to interfere with ExeGi's contractual and business relationships; and

(e) Any other and further relief as this Court deems just and proper.

Dated: August 27, 2019

Respectfully submitted,

SCHULMAN BHATTACHARYA, LLC

By: /s/ Jeremy W. Schulman
Jeremy W. Schulman

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Counsel for Plaintiff ExeGi Pharma, LLC

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff demands a trial by jury in this action of all issues so triable.

Dated: August 27, 2019

Respectfully submitted,

SCHULMAN BHATTACHARYA, LLC

By: /s/ Jeremy W. Schulman
Jeremy W. Schulman

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